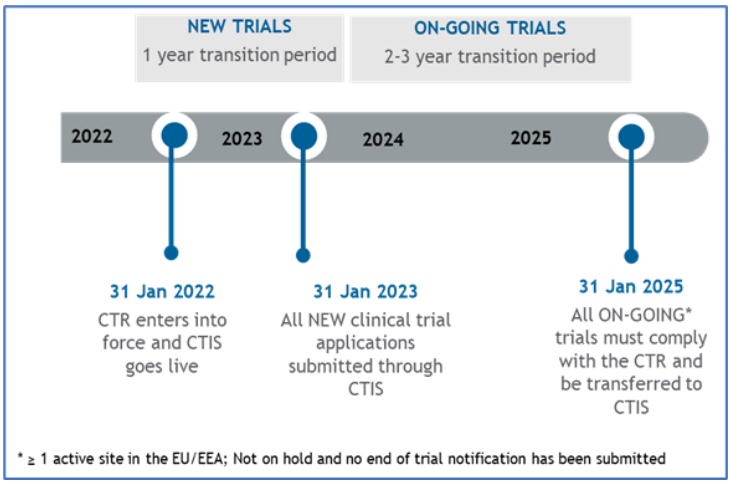
Preparing for the Clinical Trials Regulation (CTR)

What is the CTR?

- The CTR (Regulation (EU) No 536/2014) replaces the EU Clinical Trials Directive and local implementing legislation and provides the requirements for conducting clinical trials in member states of the European Union (EU)
- The CTR aims to harmonize EU clinical trial requirements and has a single point for communication with the competent authorities and ethics committees in the EU and the European Economic Area (EEA), the Clinical Trials Information System (CTIS)

Transition Period

- The Regulation came into force on 31 January 2022 with a transition period to 31 January 2023 for new clinical trials and up to 31 January 2025 for ongoing trials
- Ongoing trials can be transitioned at any point during the three-year transition period
- Sponsors are advised to do this early to ensure they have enough time before 31 January 2025 to complete all the necessary steps



- Clinical trials that are transitioned must meet all the mandatory data and document requirements of the CTR including a harmonized or consolidated protocol, taking into account all protocol versions in the EU; this may require substantial amendment in preparation for transition
- It is therefore imperative that all Sponsors of EU clinical trials are prepared for the CTR and have a clear strategy in place for the submission of new trials and transition of existing ones

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Considerations for Trials Conducted Under the CTR

- The CTR represents a massive change in the way in which clinical trials are regulated in the EU
- Some of the key elements Sponsors should consider are highlighted below
- Please do reach out to us at Boyds for any help in determining your strategy for the transition to the CTR and in preparing for implementation

Documents and submissions

- Core documents requirements harmonised
- Local document requirements remain e.g. ICF, fees, translations, legal requirements etc
- Single point of communication with CAs and ECs (CTIS)

Reporting oblifations

- New obligations for reporting of milestones/actions during the trial, including both local and global milestones
- Addition of safety reporting procedures
- Reporting of serious breaches of GCP, protocols and the regulatiuon

Transparency

- By default, CTIS publicly accessible
- Provisions put in place to ensure legitimate interests protected
- Publication of some elements can be deferred under certain circumstance but must be carefully identified in advance